United States Department of Agriculture
Research, Education, and Economics

ARS ☐ CSREES ☐ ERS ☐ NASS

Policies and Procedures

Title: Technology Transfer in ARS

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This P&P describes policies, procedures, and responsibilities for technology transfer.

Table of Contents

1. Summary

Successful technology transfer (TT) helps ensure that society benefits from Agricultural Research Service (ARS) program. It responds to the public's right to know how tax-supported ARS research improves their health, the environment, and their quality of life. It meets the requirements of laws that mandate that ARS be proactive in transferring its technology to the private sector, including small businesses. Research is only successful if the information and technologies developed are transferred to those who need it.

ARS has been delegated authority by the Secretary to administer the patent and license programs for USDA. The ARS Office of Technology Transfer (OTT) is assigned the responsibility for protecting intellectual property, developing strategic partnerships with outside institutions, and performing other appropriate functions that enhance the effective transfer of ARS technologies to users. To accomplish this, OTT is organized around broad functional areas: Patenting, Licensing and Administrative and Partnerships. The Administrative and Partnerships Section conducts the day-to-day operations, coordinates the development of TT policy, signs Cooperative Research and Development Agreements (CRADAs) and Material Transfer Research Agreements (MTRAs) and is responsible for the Agricultural Research Partnerships (ARP) Network. The Partnership Section is also responsible for the coordination of the agreement approval process with the Office of National Programs (ONP). The Patent Section assist the scientist in protecting intellectual property (IP) rights, coordinate Invention Reports (IRs), prepare and prosecute patent applications, and oversee any patent applications prepared by contract law firms. The Licensing Section negotiates licenses for ARS IP and biological materials. Technology Transfer Coordinators (TTCs) are located in the field and have overall responsibility to assist in any way possible to facilitate and effectively transfer ARS technologies. They serve as liaison with scientists, line and program managers in ARS, university partners, users, and the private sector; they also negotiate CRADAs, other TT agreements and some licenses.

This Policies and Procedures pertains to: (1) reporting inventions, (2) patents, (3) Plant Variety Protection Certificates (PVPC), (4) licensing, (5) distribution of license income (including awards to inventors), (6) CRADAs, and (7) other agreements used in TT. It sets forth ARS policies, procedures and responsibilities for TT, and includes guidelines for inventors.

2. Authorities and Forms

- AD-416, Research Work Description-Research Resume
- AD-417, Research Work/Project Description, Classification of Research
- AD-421, Research Work Unit/Project Description, Progress Report
- ARS-425, Authorization to Apply for and Use Funds from Outside Sources
- ARS-451, Research Agreement Fact Sheet (Local reproduction)
- Departmental Regulation 5700.01, Patents
- Executive Order 12591, Facilitating Access to Science and Technology

- Presidential Memorandum to the Heads of Executive Departments and Agencies on Government Patent Policy, February 18, 1983
- 7 CFR, 1999 edition, section 2.65(a), Delegations of Authority to the Administrator, ARS, subparagraphs (11), (22), and (58)
- 37 CFR, part 404, Licensing of Government Owned Inventions
- 37 CFR, part 501, Uniform Patent Policy for Rights in Inventions Made by Government Employees.
- 7 USC 450(a), Cooperative Research Projects; Agreements with, and Receipt of Funds From State and Other Agencies
- 7 USC 2321 et seq., Plant Variety Protection Act
- The following parts of the Federal Technology Transfer Act of 1986 (FTTA):
    - 15 USC 3710a, Cooperative Research and Development Agreements (CRADAs)
    - 15 USC 3710c, Distribution of Royalties Received by Federal Agencies
    - 15 USC 3710d, Employee Activities
- 35 USC 200-209, Bayh-Dole Act, Patent Rights in Inventions Made with Federal Assistance

3. Invention Reports and Intellectual Property Protection

In many cases involving ARS research, some form of IP protection is required to induce a commercial partner to invest in a technology and ultimately engage in large-scale manufacturing and distribution. Most protection of intellectual property in the Federal Government is done through patents. Utility Patents protect a newly invented product, process, machine, or composition of matter. Plant Patents protect a unique plant variety that is produced vegetatively. Plant Variety Protection Certificates are issued for plants that reproduce sexually (by seeds) or by tubers. Once the patent is issued, protection extends for a period of 20 years from the date the patent application was filed. The first consideration in deciding whether or not to seek a patent is to ask if protection will enhance the likelihood that the technology will be transferred to the private sector. Many excellent original ideas are best transferred to those who need the information by scientific publications or other methods that do not involve patenting, such as electronic media, field days, demonstration projects, or public release.

3.1 Policy

ARS policy is to use the patent system to promote the utilization of inventions arising from its research, to ensure that sufficient rights in inventions are obtained to meet the needs of the Government, and to bring the invention to practical application. Therefore, ARS has a judicious patenting policy.

ARS recognizes that patents represent documentation of research accomplishments and will consider patents, along with other factors, as evidence of research productivity in evaluating scientist performance annually as well as under the Research Position Evaluation System.

Inventors shall take prompt action to report inventions made as a direct result of their official duties. In addition, when an ARS scientist develops/invents a new material the new material needs to be reported through the filing of an ID. To ensure that their inventions are protected in a timely manner, inventors shall submit an Invention Disclosure (ID) through ARIS as soon as there is enough information to evaluate the invention. Inventors should contact a patent advisor and/or TTC to determine if there is sufficient information for submitting an invention disclosure. It should at least be reduced to practice and know what its commercial potential is. Waiting to submit an ID until after a manuscript disclosing the invention is submitted for ARS clearance for submission to a journal may delay publication of the manuscript in order to permit sufficient time to draft and file an associated patent application.

It is the decision of ARS, not individual scientists, as to whether or not an application for a patent or PVP Certificate will be filed. Generally, the ARS will only file for patent protection when it is determined that a patent will enhance Technology Transfer. Moreover, ARS will only file for patent protection on those inventions that have been adequately described, have been reduced to practice, and have been evaluated to determine that they appear to have significant commercial potential. Patent applications will generally be filed no later than one year from the date that the invention is recommended for patenting by a Patent Review Committee (PRC), provided that information or data necessary to support the scope of the invention is complete and made available to the PA by the inventor.

Under U.S. patent law, a U.S. patent application must be filed within one year after a printed publication, public use or sale, or other enabling public disclosure of the invention. If an invention is to be, or has been made publicly accessible, the Patent Advisor (PA) must be promptly advised so that the PA will have sufficient time to prepare and file the case at the U.S. Patent and Trademark Office (PTO). Most foreign countries require that patents be filed before public disclosure, which may be as simple as talking about it in a meeting with non-ARS personnel. Hence, any public disclosure prior to filing a patent application will likely jeopardize foreign patent rights, and will also start the one year bar on filing a patent application in the U.S. ARS scientists are therefore advised to consult with their TTC or a Patent Advisor prior to making any public disclosure of an invention.

USDA is entitled to patent ownership of an invention. As a condition of employment, ARS scientists must assign their rights in their inventions to the Secretary of Agriculture who represents USDA. ARS does not assign its ownership of inventions to other parties.

Patent maintenance fees are required by the U.S. Patent and Trademark Office. These fees are due at intervals of 3 ½, 7 ½, and 11 ½ years during the life of the patent. If the fees are not paid, the patent lapses and the invention falls into the public domain. General ARS policy is to pay the first 3 ½ year maintenance fee, since activities to locate appropriate potential licensees take time. Criteria used to determine whether or not to pay

the subsequent fees are the similar to those used by Patent Committees for determining whether or not to seek a patent.

If ARS decides not to apply for domestic and/or foreign patents on an invention or to abandon or otherwise not pursue commercialization of a patent, the inventors may be entitled to ownership of patent rights under one or more authorities cited above. If interested, the inventor should seek advice from the USDA Office of General Counsel (OGC), Deputy Assistant General Counsel for Patents (DAGCP), however, returning of patent rights may create a conflict of interest situation should the scientist-inventor attempt to exploit the patent commercially or otherwise benefit from it financially.

ARS policy is to obtain utility patents on plants or transgenic animals on a case by case basis. Primary consideration will be given to whether IPR are necessary to speed transfer of a new plant or animal invention into commercial trade, if protection is necessary to permit widespread availability of the plant or animal variety, or if protection will enhance international competitiveness of domestic producers. It is ARS policy to ensure that all plant varieties developed by ARS are available for breeding.

3.2 Procedures

3.2.1 Reporting Inventions

The ARS scientist, as part of their Technology Transfer Strategy, should contact their respective TTCs and in some cases their PA for assistance as soon as they believe they have made, or are about to make, a new invention but definitely no later than when starting preparation of a presentation or scientific manuscript that reports the associated research results.

Early reporting to the PA may save the scientist considerable time by determining whether the invention is patentable, and by giving the scientist advice on what information might be needed to develop a good patent application. The PA can also help the scientist protect his/her IPR by resolving questions as to what would constitute public disclosure of the invention.

The next step is for the scientist to submit an ID using the Invention Disclosure Form located in the Agricultural Research Information System (ARIS). This confidential document is not available to the public and requires approval from line management (i.e., as appropriate) Research Leaders (RL), Center Director (CD), Location Coordinator (LC), Laboratory Director (LD), Center Director (CD) and Area Office (AO). This approval process keeps line management fully informed about discoveries made in ARS laboratories. The ID provides information on the technology, commercial potential, related publications that may affect patentability, advantages over the state of the art, and possible inventors. It is worth noting that even if the TTC/Scientist/PA do not believe that an invention is patentable, the ID should still be filed.

3.2.2 Patent Review Committee

The Patent Review Committee (PRC) is an important, and confidential part, of the ARS patent process. PRCs are established based upon a subject matter area. Currently, there are three PRCs- Life Sciences, Chemical, and Mechanical and Measurement. Each PRC is composed of OTT licensing, patenting and agreements staff, Area Technology Transfer staff, and scientists who have the appropriate subject matter expertise. National Program Leaders of National Program Staff (ONP) and representatives from the Area Office may also attend the PRC. The scientists are the only voting members on the PRC.

In addition to attendance at PRCs, OTT seeks ONP input through written communication prior to the PRC. PRCs meet periodically, but an individual case should be reviewed within three months after a PA has determined that an invention disclosure is complete. For each case, an in-depth reviewer who is one of the scientists on the PRC, contacts the inventors, line managers, other scientists, etc., to obtain additional information that might be needed in reaching a decision whether or not to prepare and file a patent application. Several factors are considered by the PRC in reviewing each case in addition to the question of patentability, which is preliminarily assessed by the PA. These include:

- Would a patent likely play a significant role in transferring the technology to the ultimate user beyond what could be achieved through publication? How would the patent enhance the transfer of the technology? Is the invention of sufficient scope to justify patenting?

- Would a patent on this invention be enforceable, i.e., is the invention drawn to, or does it employ a unique and readily identifiable material or device which could be bought or sold?

- Would stakeholders support the patenting and licensing of this technology? Is there current commercial interest in the invention or a high probability of commercialization in the future? Provide the names of any companies and contact information that you think may be interested in collaborating to further develop/ commercialize this technology through a CRADA and/or SBIR proposal.

- Is the magnitude of the market relative to the cost of commercialization large enough to warrant a patent?

- Do you know of any ARS or non-ARS patents, pending patent applications, invention disclosures, or research that could impact the technology described in this invention disclosure?

- Is the invention ready to write as a patent application right now if approved by the committee?

Two recommendations are available to the PRC based on the answers to these questions: they may approve proceeding with the patent application or suspend for further action. Further patenting decisions are made by the Assistant Administrator of OTT or a designated official. Once OTT makes a decision, the result of the PRC is communicated to the inventor in a letter which communicates the decision and the fact there will be a teleconference to discuss the decision. The teleconference helps the inventor understand the reasoning behind the decision and enables him or her to devise further TT strategy for their research. A scientist who disagrees with the decision may file an appeal with the Assistant Administrator, routing it through the appropriate RL and Area Director.

3.2.3 Patents

Once an invention disclosure is approved and the necessary information provided to the PA by the inventors, a patent application is prepared. Prompt input from the inventors is critical. Preparing and filing a patent application with the U.S. Patent and Trademark Office (PTO) may take up to one year depending on the complexity of the application, the response time of the inventors, and the backlog of applications in OTT. The filing fee of $1600 or higher (2015 Fees) is paid by the inventor's Management Unit. All other fees, such as the prosecution fees, issue fee, maintenance fees (every four years) and foreign filing costs are paid by OTT from the license revenue account (LRA).

When ARS enters into partnerships with other institutions which result in jointly owned IP, OTT usually retains the right to prepare and prosecute patents. That right may be waived, at OTT's discretion, to a co-owner of an invention, or to a CRADA partner for an ARS solely owned invention. The other party must request the waiver in writing to the PA responsible for the invention disclosure. After review, the PA may grant the waiver, however, the PA and the USDA DAGCP must both be listed as Agent and Attorney of Record, respectively. The filing party must provide the PA with copies of the application, all documentation, notices from the PTO, and updates on prosecution. ARS retains the right to rescind the waiver if circumstances change and it is no longer in the Agency's best interest to allow the outside entity to continue prosecution.

ARS inventors should not sign any documents relating to intellectual property rights provided by any outside entity or its legal representative without prior review and approval by the PA. OTT may also determine that contracting patent preparation with an outside law firm is in the best interest of ARS in obtaining a patent. Such a decision is usually based on time constraints or an unusual subject matter area. OTT selects the law firm and requires that a PA and the DAGCP liaison be Agent and Attorney of Record, respectively. Preparation expenses are usually paid by OTT from the LRA, however, the inventor's laboratory may pay in cases where OTT has decided not to pursue patenting of the invention. OTT generally retains authority to prosecute the patent application before the PTO.

3.2.4 Public Disclosure of the Invention

Information released about an invention can result in the loss of IPR. Disclosure, for example, can be as simple as publishing an abstract, presenting a poster at a scientific meeting, discussing the discovery at a meeting with non-ARS participants, or putting the information on the Internet (this includes electronic reports in the ARIS that ARS makes available to the public). If there is a disclosure before filing for a U.S. patent, foreign patent rights are ordinarily lost, and U.S. patent rights must be sought as soon as possible. Once the domestic patent application has been filed, there is a one year period from the date of domestic filing to file for foreign rights, provided that there was not a public disclosure prior to the domestic filing. ARS scientists must contact their PA prior to making public presentations or release materials or technologies that may have associated IP.

3.2.5 Inventorship and Ownership

Inventorship is determined by patent law. Consequences of inaccurate listing of inventors on patents is more severe than the inaccurate listing of authors on manuscripts. Inventorship, unlike authorship, has legal implications. Wrongfully including someone on a patent application who is not an inventor, or leaving off someone who is, can result in the challenge and invalidation of the patent. Any doubts about inventorship should be brought to the attention of the PA when an invention is first submitted or as soon as doubt arises. The PA will then make a determination of who is actually an inventor after interviews and collection of information on each person's contribution to the invention. Ownership (rights) is another key issue in patents. USDA, like most organizations whether public or private, requires inventors to assign (transfer) their rights of ownership to the organization as a condition of employment. In ARS, this includes both domestic and foreign rights. The owner, not the inventor, licenses the patent and receives any income generated (see Section 4). IP developed by government researchers is, and remains, Government Property and may only be transferred to others under set procedures. A common misconception is that providing funds and materials results in ownership. Any document originating from an outside entity that addresses IP or IPR must be reviewed by OTT or a TTC for conformity with law and ARS policy before signing.

3.2.6 Plant Patents (PP) and Plant Variety Protection Certificates (PVPCs)

Plant Patents (PP) cover plant cultivars propagated asexually (tissue culture, cutting, grafting, etc.). They are prepared by a Patent Advisor and the ARS scientist and processed by the PTO. Whether PPs allow for the use of the cultivar in breeding programs without permission of the PP holder has not been resolved in court. ARS and others believe that the spirit of the law (exclude others from asexually reproducing the plant) allows for cultivars with PP to be used in breeding. The cost of filing a PP application is approximately $1600 which is paid by OTT and recovered through licensing fees. There are no maintenance fees.

Plant Variety Protection Certificates (PVPCs) cover plant cultivars propagated sexually (by seeds) or by tubers (like potatoes). They are prepared by the ARS scientist in consultation with the ONP and processed by the USDA Plant Variety Protection Office, rather than the PTO. Once the application for a PVPC is completed, OTT submits the application to the PVP Office. PVPCs allow for the use of the cultivar in breeding programs without permission of the PVPC holder and also permit farmers and growers to save seeds for their own use. The cost of filing a PVPC application is approximately $3,652 which is paid by OTT and recovered through licensing fees. There are no maintenance fees. Laws governing PVPCs do not require identifying breeders, only the owner(s). However, an organization must have a breeder of the variety to be an owner. ARS's policy is to list its breeders on Plant Variety Protection Certificates (PVPCs).

PP and PVPCs apply only to the U.S. but many foreign countries have a system known as "Breeder's Rights" which is a combination of a PP and a PVPC.

4. Licensing (patents, plant materials and biological materials)

In order for an individual or entity to commercialize an invention covered by a patent which they do not own, the party wishing to commercialize must have a license from the patent owner. The USDA technology licensing program grants licenses to qualified businesses and individuals who wish to commercialize inventions resulting from federally supported research performed at USDA laboratories and research locations.

The USDA technology licensing program is administered by OTT. Licenses may be exclusive, co-exclusive or nonexclusive. They may be for all fields of use or limited to a specific field of use. Revenues from licenses may include execution fees, minimum annual royalties, milestone payments and royalties (usually a percentage of net sales). For non-CRADA inventions, a notice of ARS' intent to grant an exclusive license must be published in the Federal Register in accordance with Federal Regulations (37 CFR 404). Other parties who may also want a license have 30 days to submit a written objection to the granting of the exclusive license and must submit a complete license application to support their objection. If there is more than one qualified domestic applicant, then non-exclusive licenses may be issued to all qualified applicants.

4.1 Policy

Federally-owned inventions must be licensed in accordance with the terms, conditions and procedures prescribed under various statutes and regulations.

The key provisions are summarized as follows:

- Only protected IP, (i.e., a patent application, issued patent, or PVPC) and patentable biological materials can be licensed. ARS does not have statutory authority to license other forms of government property.

- Application for a license must be addressed to the Federal agency having ownership of the invention. In the case of USDA, applications must be addressed to the Technology Licensing Program Coordinator, OTT, ARS.

- A license may be granted by the Federal agency only if the license applicant has supplied the agency with a satisfactory plan for the development and marketing of the invention and has provided evidence of capability and intention to fulfill the submitted plan.

- There is a preference for small business applicants if they are equally qualified.

USDA/ARS often has jointly owned inventions, especially with universities. ARS can license the rights to these inventions to the co-owner if it is in the Agency's best interest to do so.

Licensees reimburse ARS for domestic and foreign filing, prosecution, and maintenance costs.

ARS permits its inventors, where practicable, to participate in the development of their inventions by permitting them to provide technical assistance to licensees.

Because of conflict of interest rules, inventors shall not participate in license negotiations to establish fees and royalties. Inventors and RL's may furnish advice on license strategy and negotiations
ARS strongly supports the principle of the "research exemption" to patent rights. Accordingly, ARS does not in-license technologies or patents for use in ARS research programs, nor does ARS require others to obtain a license for use of ARS technologies in research, or permit a licensee of ARS patented technology to require licenses for research use.

4.2 Procedures

37 CFR 404.8 sets forth the information that must be provided by a license applicant. For the convenience of the applicant, USDA has itemized the information needed on Form AD-761, which is included in the License Application Package. The information submitted is used to determine whether the applicant has both a complete and sufficient plan for developing and marketing the invention and has the necessary manufacturing, marketing, financial and technical resources to carry out the submitted plan. Under the provisions of 37 CFR 404.14, any plan submitted by a license applicant may be treated as privileged and confidential and not subject to disclosure under the Freedom of Information Act (FOIA, 5 U.S.C. 552).

All members of OTT can provide general information regarding the licensing program, and information is also available at the OTT Internet site (http://ars.usda.gov/Business/Business.htm).

License Application Packages are available from:
Coordinator, Technology Licensing Program
USDA, Agricultural Research Service
Office of Technology Transfer
5601 Sunnyside Avenue
Beltsville, MD 20705-5131
Phone: (301) 504-5989
Fax: (301) 504-5060

The Technology Licensing Section is available to answer any questions concerning the license application process, how to complete the license application form, and license agreement terms. Furthermore, this information is available on the OTT website.

5. License Income

5.1 Policy

ARS license income is distributed in compliance with the Federal Technology Transfer Act of 1986 (FTTA, 15 USC 3710c) which authorizes specific uses for income from inventions: incentive awards to the inventors; expenses for prior art searches; patent filing costs; costs associated with administration of patent activities; licensing and administration expenses; rewards to employees for TT activities, including the annual ARS TT awards; and activities that increase licensing potential for transfer of technology (salary expenses related to some positions in OTT).

ARS inventors collectively share, as an incentive award, the first $2,000 of license income received by ARS for a particular invention in each calendar year, plus 25% of any additional income received during the same year. An individual inventor may not receive more than $150,000 in a calendar year for all inventions that are licensed. For licenses negotiated prior to March 7, 1996, the inventors share is 25% of the total income received each year.

This payment shall not affect the entitlement of the inventors to any regular pay, annuity, or award to which they are otherwise entitled or for which they are otherwise eligible or limit the amount thereof. ARS employee(s) who leave ARS receive license income award(s), provided they were an ARS employee at the time the invention was made. Heirs of an estate of a deceased ARS inventor receive decedent's license income award(s). The amount of this payment does not change even if an ARS employee leaves ARS or is deceased. Payments will continue until the license agreement is no longer in effect.

5.2 Procedures

The Legal Instruments Examiner (LIE) monitors payments of licenses and sends notices to the licensee where needed for royalty income and reports.

The Foreign Patent Specialist monitors domestic maintenance fees and foreign patent filing costs and notifies licensees when reimbursements are due.

When checks are received from the licensee, they are either processed by the LIE (for running royalty payments and minimum annual royalty payments) or by the Foreign Patent Specialist (for patent cost reimbursements). The LIE calculates the inventor incentive award and prepares the disbursement memorandum for processing by the Financial Management Division (FMAD). The checks and disbursement memoranda are forwarded to the appropriate office in FMAD where the checks are then deposited in the OTT LRA.

Using the amounts listed in the disbursement memorandum, FMAD notifies NFC to issue payments to the inventors for their awards.

6. Partnering with Outside Organizations

Agreements with outside organizations, whether public or private, produce many direct benefits. They allow research scientists to obtain expertise, proprietary products, and information that would not otherwise be available to them. Hence, agreements can markedly speed up the research process and greatly shorten the time required to get a problem solution to those who need it. Finally, agreements can bring in outside funds to leverage limited research dollars. TTCs deal directly with the scientists at field locations to negotiate agreements, assist in the patent process, act as liaison with private industry and, in some cases, negotiate licenses. The selection of the type of agreement to use is important. It is not just a matter of choice, but often a matter of law, regulation, or policy. Different situations require specific types of agreements and actions. Regardless of the type of agreement, the subject area must be within the mission of the specific laboratory entering into the agreement. Sometimes only one type of agreement permits a desired outcome. Discussed below are some of the agreements used in TT.

Outside organizations that are in position to help a scientist or the ARS with Technology Transfer include universities, private companies, and trade associations. Scientists are often in the best position to identify a potential research partner or licensee, but there are times when they may need assistance in finding a suitable candidate. The Technology Transfer Coordinators can provide support in these cases, and the Agency's Agricultural Research Partnership Network (ARP) can also be enlisted for help. The ARP is comprised of various State and local economic development entities across the country, and there are innumerable private sector businesses that are reachable through this network. OTT periodically sends notices to the ARP, advertising potential CRADA and licensing opportunities. An ARS scientist wishing to have a notice distributed to the ARP should contact his or her TTC, or the ARP Liaison in OTT.

7. Cooperative Research and Development Agreement (CRADA)

This is the most formal agreement available for cooperative research. There are two aspects of a CRADA that make it a unique type of agreement. First, it gives the cooperator the right to negotiate for an exclusive license to a CRADA subject invention that is solely owned by ARS or jointly-owned by ARS and the Collaborator and is first conceived or reduced to practice under the scope of work of the CRADA. Second, it permits ARS, at its option, to keep information developed under the CRADA confidential for up to five (5) years if such information would have been proprietary had it been generated solely by the cooperator. ARS is required to keep confidential indefinitely any trade secret or commercial or financial information that is privileged or confidential given to ARS directly by the Cooperator, unless the information becomes publicly available from a source other than ARS. CRADAs are developed by scientists and TTCs, approved by NPS and line managers, and signed by OTT on behalf of ARS.

7.1 Policy

It is ARS policy to implement and take advantage of the authorities provided in the FTTA (15 USC 3710). Scientists and TTCs are authorized to seek out opportunities for CRADAs with Cooperators provided the following criteria are met:

- All parties to the CRADA must have a mutual interest in the CRADA's objectives and the research work must be consistent with the ARS and Management Unit’s mission as well as the CRIS project goals and objectives.

- CRADAs may or may not have incoming funds, but both partners must actively participate in the research. In addition to intellectual input and proprietary information, such participation may involve contributions of personnel, equipment, supplies, materials, facilities, etc. ARS is not authorized to contribute funds to another party under a CRADA.

- CRADAs should not be used simply as a means to bring in outside funds, nor should they normally be used to test, develop, or validate a company's product.

CRADAs are appropriate vehicles for:

- Transfer and/or further development of ARS technology.

- Research combining ARS’s and a Cooperator’s intellectual property or technology.

- Discovery and development of new and/or improved products and or services.

Inventions arising under the scope of the CRADA that are either solely owned by ARS, or co-owned by ARS and the Cooperator, are offered to the Cooperator for licensing in at least one field of use on an exclusive basis without Federal Register notice. As with any ARS license, the Cooperator must submit a complete and sufficient license application which includes a business plan for commercialization of the invention.

ARS personnel handle TT documents expeditiously and appropriate procedures are used to protect information identified as proprietary.

ARS scientists/inventors may work closely and directly with Cooperators to help commercialize technology based on the scientists' research.

7.2 Procedures

7.2.1 Development of a CRADA

ARS TT opportunities are announced through the ARP Network, meetings, symposia, workshops, conferences, and/or in the print or electronic media, and scientists are contacted by potential Cooperators. Formal competition is not required except as deemed necessary by the Assistant Administrator for Technology Transfer.

The ARS scientist and Cooperator identify the area of cooperative research work.

The ARS scientist contacts the Area Technology Transfer Coordinator (TTC) and the two consult and receive verbal approval from the RL to proceed with developing the CRADA. The next step is to contact ONP to determine if the collaborative research fits within ARS mission prior to negotiations. If the CRADA concerns a sensitive area such as plant breeding and animal biotechnology, documentation of ONP approval prior to negotiations is required, as well as approval from the Institute/Laboratory/Center Director and Area Director. The ARS scientist and Cooperator develop a brief description of proposed cooperation and forward it to the TTC to draft the CRADA for review. The template for drafting the CRADA is the current version of the “Generic CRADA” found on OTT’s Website at http://www.ars.usda.gov/AboutUs/Docs.htm?docid=24747

The reviewed draft CRADA, with the budget and supporting documentation, is then forwarded by the Area Technology Transfer Assistant (TTA), with approval from the Area Office, to OTT’s Partnership Liaison (PL). The PL obtains the appropriate internal ARS clearances and checks the document for completeness. While the CRADA is being reviewed by the PL, the scientist’s support staff enters the CRADA into the Agriculture Research Information System (ARIS) for formal internal approval. Once the CRADA has been formally approved through ARIS, the OTT’s Authorized Departmental Officer (ADO) signs the CRADA and sends it to the Cooperator for signature. Once signed, the CRADA is returned to the TTA for uploading into ARIS’s e-Green and TINS

7.2.2 Award Document

The award document consists of:

- The REE-451.
- The CRADA prepared as described above.

The distribution of the award document is:

- If ARS is receiving funds from the cooperator, the ARS Business Center's budget officer receives a copy of the award documents or can access them through e-Green.
- Cooperator (manually signed original).
- ADO/OTT Official File (manually signed original).
- ARS PI (photocopy).

7.2.3 Amendments or Revisions

Proposed amendments or revisions to existing CRADAs are processed by the ADO/OTT in consultation with the PI, the Cooperator, ONP, the AD, and the OTT staff. Procedures are designed to be as expeditious as possible. All amendments must be made in writing. Prior to official amendment, the PI will be asked to submit a progress report, a new budget and a revised statement of work.

7.2.4 Administration

The PI and Cooperator shall submit work progress reports to each other at the frequency agreed upon in the CRADA and at closeout/termination.

The ARS and the Cooperator shall submit invention reports to each other as set forth in the CRADA.

The Budget Officer will:

- Provide fiscal and accounting support to the PI.
- Send the Cooperator an annual financial statement (if required) when funds are received by ARS.
- Verify final payment on all valid obligations with the National Finance Center and recommend return of funds not used to the contributor(s).

The ADO/OTT periodically contacts the PI and the Cooperator, as necessary, in order to monitor the accomplishment of the CRADA and the ADODR's adherence to his/her duties under the CRADA.

7.2.5 Closeout

The TTA/TTC notifies the PI that a CRADA is due to expire prior to expiration. The notice specifies the documentation necessary to close out a CRADA. Such documentation typically includes:

- Final Technology Report.
- Description of accomplishments (new products or services).
- Report of all inventions.

8. Other Types of Cooperative Agreements

Agreements with outside organizations, whether public or private, produce many direct benefits. They allow research scientists to obtain expertise, proprietary products, and information that would not otherwise be available to them. The selection of the type of agreement to use is important. It is not just a matter of choice, but often a matter of law, regulation, or policy. Different situations require specific types of agreements and actions. ARS has a number of technology transfer agreements. Detailed Policies and Procedures for other types of cooperative agreements are found in P&P 321.1.v.3 on Requirements for Seeking and Accepting Incoming Research Agreements, P&P 705.0 v.3 on Memorandum of Understanding (MOU) Agreements, P&P 704.0.v.2 on Research Support Agreements, P&P 324.0 on, Reimbursable and Trust Fund Agreements., Chapter 2400 of the Financial Management Manual and the Extramural Agreements Manual

Given below are brief descriptions of these agreements as they relate to TT.

8.1 Funded and Unfunded Cooperative Research Agreements

These agreements are similar to CRADAs but lack the provision for exclusive licensing of ARS inventions. Confidentiality provisions apply to the Cooperator's proprietary material, but information developed by ARS during the agreement can be withheld only to protect IP rights until a patent application is filed, normally no more than one year. The TTC may assist in the negotiation and preparation of these agreements.

8.2 Material Transfer Agreements (MTAs)

A Material Transfer Agreement documents and sets the conditions for the loan of specific materials – it does not transfer ownership. MTAs are used when a scientist desires to provide material to someone outside of ARS but wants to maintain control over the

material and also avoid public disclosure (use). A MTA is also used to bring in material from parties outside ARS. This agreement states specifically what the material is, what it can be used for, restricts giving it to a third party without permission, and prohibits commercial use. The MTA template can be found on OTT's SharePoint site. The MTA is signed by the Cooperator's representative, TTC, ARS scientist, and ARS Research Leader. When a scientist is asked to sign either 1) an MTA from an outside organization in order to receive research material; or 2) when the company requests changes to the ARS MTA template, the MTA MUST be reviewed and approved the TTC prior to ensure that the provisions are acceptable to ARS. Many NPLs have requested to review MTAs prior to signature.

8.3 Non-Disclosure Agreement (NDA)

A scientist should use a NDA when s/he wants to discuss unpublished information or data with someone outside of the Agency. NDAs should also be used when that ARS wishes to share a patent application with an outside entity before the patent issues or the patent application publishes. Discussion of information within ARS is not considered public disclosure and does not require a NDA, but colleagues should be cautioned not to discuss or disclose the information to outsiders. The NDA template can be found on OTT's SharePoint site. NDAs are signed by the cooperator's representative and the ARS scientist.

8.4 Material Transfer Research Agreements (MTRAs)

MTAs only allow for the transfer of materials, but not engagement in joint research between the provider and the recipient of the materials. In order to enable some collaborative research with the material, the Material Transfer Agreement and the Cooperative Agreement authorities were combined to create the MTRA. This agreement does not convey rights to negotiate exclusive licenses to any intellectual property arising from the research. It is intended as an early stage opportunity for proof of concept that may lead to more extensive research that would be conducted under a CRADA.

9. Summary of Responsibilities

9.1 Authorized Departmental Officer (ADO)

Per their delegated authority, the ADO has responsibility for establishing, administering, and terminating agreements with outside entities on behalf of ARS.

9.2 Authorized Departmental Officer, OTT (ADO/OTT)

Conducts the specific responsibilities of the ADO for CRADAs, using the procedures outlined in Section 7.

9.3 Principal Investigator (PI)

ARS employees serving as PIs on ARS extramural research agreements such as Memoranda of Understanding, Cooperative Agreements, Grants, Research Support Agreements, Non-Assistance Cooperative Agreements (NACA) previously called Specific Cooperative Agreements (SCAs), CRADAs, etc. are responsible for

- Promptly reporting inventions made under these agreements to the Patent Coordinator.
- Keeping AD and NPL informed of program implementation and progress.
- Developing CRIS documentation and submitting it to the Area Program Administrative Assistant (or equivalent) for action (AD-416/417, and ARS-425).
- Keeping the ADO informed of activities under the CRADA and forwarding copies of required correspondence to the ADO.
- Assuring that confidentiality of the CRADA is honored.

9.4 Deputy Assistant General Counsel for Patents (DAGCP), Office of General Counsel (OGC), USDA

- Files and prosecutes selected patent applications.
- Determines ownership of inventions.
- Takes other necessary and appropriate legal actions.
- Gives advice and counsel pertaining to patent license policies, regulations, and statutory authority.
- Determines if rights to a patent are to be waived to the inventor if the invention is not selected for patenting. This determination is made in coordination with line management, NPS and OTT.

9.5 Information Staff

- Provides appropriate public information supporting the TT efforts of ARS through the appropriate media.

9.6 Line Managers (RLs, CD, LD, ID, ADs)

- Assures that the ARS Patent Program is being used by all ARS employees whose research leads to an invention.

- Assures that inventions and patents are recognized in performance evaluations and RPES write-ups.

- Expedites the orderly processes data to ensure timely reporting of invention disclosures to PAs. Such actions include but are not limited to:

    - Promptly reviewing Agricultural Research Service Invention Tracking System (ARSITS) and taking action on the IR by accessing the signature screen, entering the signer's name or four digit signature code, and entering "A" for approval or "D" for disapproval.

    - Exercising approval authority analogous to that of scientific manuscripts to assure that IRs are of a quality to reflect favorably on ARS and that listed inventors are appropriate, similar to the review of authorship of manuscripts.

9.7 Office of Technology Transfer

OTT, a part of the Office of the Administrator, has the delegated authority for implementation of the FTTA and Executive Order 12591. In this capacity, OTT manages the ARS Technology Transfer Program.

Establishes policy and procedures for processing of IRs, patent application preparation, and prosecution of patent applications.

- Makes final determination on Patent Committee recommendations on IRs.

- Consults with NPS on intellectual property protection of plants and animals.

- Coordinates with ADs on the selection of PRC members.

- Assists inventors in TT activities to seek commercialization of inventions through CRADAs and/or licenses.

- Reviews and approves/disapproves any deviation from standard IP clauses in ARS research agreements (Grants, Cooperative Agreements, Specific Cooperative Agreements, CRADAs, etc.).

- In consultation with OGC, formulates USDA licensing policy and procedures.

- Negotiates, approves, disapproves, amends, revokes, terminates, and/or reissues patent, plant and biological material licenses.

- Administers licenses on (1) inventions made by ARS, (2) inventions made under ARS CRADAs, (3) inventions made by other USDA agencies, and (4) some jointly owned inventions by ARS and a University Partner.

- Pays patent maintenance fees on ARS inventions determined worthy for continuance.

- Coordinates payment of maintenance fees on inventions by other USDA agencies.

- Prepares required *Federal Register* Notices relevant to the patent program.

- Negotiates licensing terms and conditions with potential licensees, considering applicable Federal Regulations, the interest of the U.S. Government in promoting commercialization of Federal research results and the need to provide a proper reward to the inventor.

- Monitors licenses to assure annual progress reports and fees due are received, maintains patent and license records, and keeps ARS employee/inventors and other USDA agency personnel advised of activities.

- Authorizes patent awards for inventors.

- Negotiates and manages the Law Services Contract responsible for the international patent filings of USDA inventions.

- Assures the distribution of patent license income according to the FTTA as amended. License income received by ARS must be obligated by the end of the fiscal year succeeding the fiscal year of receipt.

- Prepares a yearly ARMP for estimated license income and prorates uses of such income (License Revenue Account).

- Remits promptly all license income received to the FMAD Headquarters Collection official for deposit in an appropriate account with instructions on disbursements.

- Notifies the recipient USDA inventor(s) of the amount of money they will receive, that it is taxable, and that the Internal Revenue Service will be notified.

- Has lead responsibility for coordinating the development of CRADAs.

- Works with ARS scientists, managers, and potential Cooperators to develop and process CRADAs.

- The ADO/OTT is authorized to award, administer, terminate, and closeout CRADAs, as is the Administrator, Associate Administrator, and the Assistant Administrator for Technology Transfer. The ADO works closely with each PI and follows all applicable laws, regulations, policies, and procedures.

- Carries out other activities to promote transfer of USDA technology.

- Coordinates and/or prepares TT awards for USDA inventors through appropriate officials.

- Serves as the focal point and clearinghouse for information concerning TT.

- Advises the Information Staff of developments relating to the implementation of and progress in TT activities.

- Attends trade shows, prepares written materials, and develops marketing plans of ARS technology.

9.8 Patent Advisors

- Provides counseling and patent awareness training to ARS inventors in their respective area of expertise, i.e., chemistry, biotechnology and mechanical and measurement.

- Reviews IRs and assesses patentability.

- Coordinates Patent Committee meetings to review and evaluate the potential economic and technical impact of inventions.

- Prepares and prosecutes patents subject to OGC review.

- Provides timely information to the Coordinator of the Technology Licensing Program, and Technology Transfer Coordinators about patent applications and patent status.

9.9 Patent Review Committee

- Recommends whether or not to patent the invention. (See criteria, Exhibit 2.)

- Recommends whether or not the IR needs further research data to substantiate a patent and to broaden the scope of the invention.

- Recommends whether or not the publication is appropriate to transfer the technology and that a patent application need not be filed.

- Recommends whether or not the IR be given additional evaluation for commercial potential.

9.10 Human Resources Division

- Develops and administers the ARS Technology Transfer Incentives and Awards Program.

9.11 Scientists (Inventors)

- Become familiar with the TT process through attendance at an OTT training and other means.

- Use permanently bound research notebooks, preferably Form ARS-1. Specific instructions are in the front of the notebook. Notebooks are available from the Consolidated Forms and Publications Distribution Center, 3222 Hubbard Road, Landover, Maryland 20785. To order, use CFPDC-1, Request for Forms and Publications.

- Meet critical dates in patent law due to statutory deadlines that must be met to avoid loss of valuable patent rights for both foreign and domestic applications.

- Protect intellectual property by avoiding premature disclosure, by reporting inventions in a timely fashion, and by diligent use of CAs, and MTAs.

- Forward IDs, through appropriate channels, to the PA as soon as possible but, in any case, no later than the time that a manuscript disclosing the invention is submitted for ARS clearance for publication.

- Prepare material relative to the ID sufficient for evaluation and/or preparation of a patent application. The material submitted should include a search report in the technical field of the ID with copies of references found.

- Report the publication of an invention to the PA as soon as possible. Publications include: scientific journals, trade journals, newspaper articles; abstracts distributed at professional society meetings; CRIS reports; interpretive summaries; and/or manuscripts distributed upon request.

- Not disclose an invention in a publication, presentation, or other means prior to filing a patent application in the PTO, if the invention has foreign

commercial potential. Disclosure prior to filing is an immediate bar to obtaining foreign patent protection in most countries.

- Strive to avoid disclosing inventive concepts by exercising discretion when preparing meeting abstracts, CRIS reports, and interpretive summaries by focusing on the "what" and "so what" of the research rather than critical details of the "how." Check with the PA when in doubt.

- Conduct a thorough search before preparing the ID and, if possible, forward to the PA a copy of the search with the ID. State specifically how the invention is different from the most relevant known technology found during the search.

- Provide advice to the PA to help ensure that the breadth of the claims of the patent application claims do not exceed reasonable scientific predictability.

- Assist the PA in the ongoing prosecution of the patent application by reviewing and commenting on PTO Official Actions and the references cited by the PTO Patent Examiner, IN A TIMELY MANNER, to avoid monetary penalties or loss of intellectual property protection.

- Submit requests for consideration of a PVPC or plant patent to the Plant Protection Review Committee through ARIS.

9.12 Area Technology Transfer Offices

- Represents ARS in CRADA, MTRA, and other TT negotiations, and before stakeholders.

- Approves MTAs, negotiates non-standard MTAs and Confidentiality Agreements.

- Provide advice to area Administrative Management staff regarding intellectual property rights and confidentiality issues in CAs and SCAs.

- Provides training and advice to scientist regarding TT issues.

- Serves as non-voting member of Patent Committee. Provides advice to Patent Committee regarding commercial potential of reported inventions.

- Works with scientists and OTT to market ARS inventions.

- First point of contact for the scientist, support staff and AREA office

- Supports Agreement negotiations

- Routes and tracks all agreements – from beginning to final signature
- Coordinates, sets up and facilitates all TTC meetings, webinars and conferences calls
- Sends out all OTT agreement invoices
- Enters all ARIS data for CRADAs, MTRAs, CAs & MTAs

10. Glossary

ABFO - Area Budget and Fiscal Office.

AD - Area Director.

ADO - The individual in ARS having written delegation of authority by the Administrator of ARS to enter into, administer, and close out agreements with organizations outside of ARS.

ADO/OTT - The Authorized Departmental Officer of OTT granted a written delegation of authority from the Administrator of ARS to enter into, administer, and closeout CRADAs.

AMS - Agricultural Marketing Service

ARMP - Annual Resource Management Plan.

ARIS (Agricultural Research Information System) - A computer database tracking system which allows certain parties to track the progress of IRs, patent applications, patents, and licenses.

BPMS - Budget and Program Management Staff.

CD - Center Director.

Co-Exclusive License - The licensing of an invention to a limited number of licensees (two or more).

Cooperator - Any State agricultural experiment station, State cooperative extension service, all colleges and universities, other research or education institutions and organizations, Federal and private agencies and organizations, individuals, and any other party, either foreign or domestic, receiving an award from a REE Agency.

CRADA - A joint agreement between the Federal Government and industry, foundations, or universities to collaborate in a research project as authorized by the Federal Technology Transfer Act (15 USC 3710).

CRIS - Current Research Information System.

DAGCP - Deputy Assistant General Counsel for Patents.

Exclusive License - The licensing of an invention to only one licensee.

FMAD - Financial Management Division.

FTTA - Federal Technology Transfer Act (15 USC 3710).

FR - Federal Register. An official, daily publication communicating proposed and final regulations and legal notices issued by federal agencies, including announcements of the availability of funds for financial assistance.

ID - Invention Disclosure

IP - Intellectual Property. As defined for agreements, intellectual property means the products of research that have the potential to be protected by a patent or a Plant Variety Protection (PVP).

IPR - Intellectual Property Rights.

IS - Information Staff.

Invention -An invention is any process, art, method, machine, manufacture, design, composition of matter, or any new and useful improvement thereof, or any variety of plant or other biological entity which is or may be patentable or otherwise protectable under the laws of the United States.

IR - Invention Report.

License - A written authority granted by the owner of a patent to another person empowering the latter to make or use the patented article for a limited period or in a limited territory and to make, use, or sell articles embodying the patented invention.

License Income - The fees and royalty income paid to the owner of an invention by the licensee. Royalty income is based upon commercial use (e.g., percentage of sales of an invention-based product). In addition, ARS licensees typically pay an execution fee (when the license is first put into effect) and an annual maintenance fee (while the licensee is developing the product for marketing).

LD - Location Director.

MOU - Memorandum of Understanding. An agreement between ARS and another party that sets out, in very broad, general terms, a plan for the parties to coordinate their efforts on projects of mutual interest.

MTA - Material Transfer Agreement. A legal document defining the conditions under which research or other materials can be transferred outside ARS and used among outside parties, but allows ARS to maintain control over the material and avoid public disclosure. MTAs can also be used to bring material into ARS from outside parties for research purposes.

MTRA- Material Transfer Research Agreement

NAL - National Agricultural Library

NDA – Non-Disclosure Agreement

NFC - National Finance Center.

Nonexclusive License - The licensing of an invention to more than one licensee without restriction as to the number of licensees.

NPL - National Program Leader.

ONP - Office of National Programs. The staff composed of National Program Leaders (NPLs) and associated staff at ARS headquarters in Beltsville, MD manages and leads National Programs that serve to bring coordination, communication and empowerment to approximately 800 research projects carried out by ARS.

OGC - Office of the General Counsel.

OTT - Office of Technology Transfer.

PA - Patent Advisor.

Partially Exclusive License - A license granted occasionally to a very limited number of licensees, e.g., for specific fields of use or in a specific geographic area, or both.

Patent - (1) Statutory protection granted for inventions in the United States under Title 35 of the USC; (2) similar protection for inventions granted in foreign countries; and (3) protection granted in the U.S. and elsewhere for other types of inventions and discoveries such as new plant varieties, including PVPC.

Patent Maintenance Fee - A fee required by the U.S. Patent and Trademark Office.

PI - An individual (usually the lead ARS scientist of the research) who is granted a written limited delegation of authority to represent the ADO in the administration of a

CRADA. This individual provides ongoing administrative oversight of activities that occur under the CRADA and provides scientific or technical interactions with the Cooperator on behalf of ARS.

PRC - Patent Review Committee.

PTO - Patent and Trademark Office.

PVPA - Plant Variety Protection Act (7 USC 2321 et seq.).

PVPC - Plant Variety Protection Certificate issued under the Plant Variety Protection Act.

RL - Research Leader.

RPES - Research Position Evaluation System.

TT - Technology Transfer.

TTC - Technology Transfer Coordinator.

USC - United States Code.

_____ _____

MOJDEH BAHAR Date
Assistant Administrator
Office of Technology Transfer